Remarks:

Claim 1 has been amended to cover a process for the isolation of a particulate pharmaceutical product from a high pressure process wherein the pharmaceutical product is defined as a pharmaceutically active compound and/or pharmaceutical excipient. Basis for this amendment may be found on page 7, lines 7-8 of the application as filed. The amended claim 1 particularly points out and distinctly claims the subject matter of the invention in accordance with 35 U.S.C. 112 paragraph 2.

Claim 11 has been amended to cover a particulate pharmaceutical product according to product claim 2 thus the metes and bounds of the claim are clearly identified. As such, the amended claim 11 particularly points out and distinctly claims the subject matter of the invention in accordance with 35 U.S.C. 112 paragraph 2.

Claim 2 has been amended to cover a pharmaceutical product, which product has been isolated from a high pressure, for example supercritical, process and claim 3 has been amended to cover apparatus for the isolation of a pharmaceutical product from such a process. Claim 12 has been amended to cover a process as described in claim 1 which facilitates continuous or semi-continuous formation and isolation of pharmaceutical products.

As articulated by the MPEP 706.02 (emphasis added):

"for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly."

Whiting et al. (US 5,543,057) teaches a process for the oxidation of organic compounds in an aqueous waste stream containing one or more inorganic salts or organic salt precursors insoluble under the supercritical reaction conditions. The invention of Whiting et al. addresses the problem that insoluble inorganic salts present in the aqueous stream under supercritical conditions adhere to the internal surfaces of the reactor with detrimental

effects to the reactor. By the introduction of insoluble, inert particles of sand, silica, clay, metal, ceramic, zeolite or metal oxide into the fluid stream, an alternative surface is provided to which the insoluble inorganic salts may adhere. Following oxidation in the reactor, the fluid stream is cooled and depressurized to non-supercritical conditions. The inorganic salts adhered to the insoluble, inert particles become soluble in the aqueous stream and the insoluble, inert particles are recovered in a separator. These disclosures are wholly unrelated to the isolation of a pharmaceutical product or excipient from a supercritical particle formation process since the insoluble particles are not products of the supercritical process having instead been present in particulate form throughout the entire process.

In addition to not anticipating the invention recited in claim 1, Whiting et al. clearly does not suggest or motivate the use of a radial filter within a mixing vessel. As described above, Whiting et al. discloses a method for reducing adhesion within a reaction vessel. Claim 1 recites a device for isolation of a particulate pharmaceutical product as a suspension in a non-supercritical fluid. There is clearly no motivation to modify the teachings of Katz to arrive at the claimed invention.

Conclusions:

All claim rejections being addressed in full, Applicant respectfully requests the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance. Should the Examiner have any questions regarding the foregoing, Applicant respectfully requests that the Examiner contact the undersigned, who can be reached at (919) 483-.9995

Respectfully submitted,

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/Dwight S. Walker/
Dwight S. Walker
Agent of Record
Reg. No. 63,170

Customer No. 23347
GlaxoSmithKline
Corporate Intellectual Property
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709-3398
Tel: (919) 483-9995
Fax: (919) 315-4032